



UNITED STATES DEPARTMENT OF COMMERCE  
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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. NO.
08/849,404	05/22/97	LAFFEND	L CR-9715-B
EXAMINER			

HM11/0624

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BUGATSKY, G	PAPER NUMBER
ART UNIT	

1652

DATE MAILED: 06/24/98

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 3/30/98
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- ☒ Claim(s) 2, 6, 20-31 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☒ Claim(s) 20-30 is/are allowed.
- ☒ Claim(s) 2, 6, 31 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

BEST AVAILABLE COPY

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The amendment of 3/30/98 is acknowledged. Claims 1, 3-5, 7-19, 32 and 33 have been canceled, rendering their rejections as moot. Claims 2, 6, and 20-31 are currently under consideration.

### ***Double Patenting***

The double patenting rejection of claim 22 35 U.S.C. §101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 5,633,362 is withdrawn upon further consideration.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 2 and 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,686,276 is withdrawn upon further consideration in favor of the following rejection.

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Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-16 of U.S. Patent No. 5,686,276 in view of Daniel *et al.* (1992), in light of Daniel *et al.* (1995). The claims of the patent are to a process for production of 1, 3- propane diol, with a substrate other than glycerol or dihydroxyacetone. They do not specify that the bacteria be transformed with an exogenous *dhaT* gene. Daniel *et al.* provides transformed *E. coli* which express the *Citrobacter freundii* *dha* regulon and produce active glycerol dehydratase; the presence of which is assayed by measurement of 1,3-propanediol production. They do not use a substrate other than glycerol or dihydroxyacetone. Daniel *et al.* later stated that the cosmid used in their earlier work which contained the *dha* regulon also contained the 1, 3-propanediol dehydrogenase gene (*dhaT*). In order to produce 1, 3- propane diol, with a substrate other than glycerol or dihydroxyacetone, it would have been obvious to use the transformed *E. coli* of Daniel *et al.* in the process of U.S. Patent No. 5,686,276, with a reasonable expectation of success in obtaining 1, 3- propane diol.

The provisional rejection of claims 2 and 6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 08/687,852 is withdrawn upon further consideration.

The rejection of claims 20-21 and 23-31 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,633,362 is withdrawn upon further consideration.

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**Claim Rejections - 35 USC § 112**

Claims 2, 6 and 31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of generating 1, 3- propane diol with microorganisms transformed with the *Klebsiella pneumoniae dhaB* gene, does not reasonably provide enablement for production of 1, 3 propane diol by any microorganisms transformed with any diol dehydratase gene from any other organism or with microorganisms containing an endogenous *dhaB* gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant application shows the production of 1, 3- propane diol from organisms transformed with the glycerol dehydratase gene of *Klebsiella pneumoniae*, but does not address how to purify or isolate any other dehydratase genes from any other organism. No teaching is given regarding sequence similarity either between *dhaB* genes of different organisms or between dehydratase genes in general. Indeed, Bouvet *et al.* performed an exhaustive survey of glycerol dissimilation of 1,123 strains from 128 taxa in the *Enterobacteriaceae*, and observed only 8 species and a few rare strains could anaerobically utilize glycerol (i.e. possess the *dha* regulon). It is deemed that the scope of the claims is much broader than the enablement provided by the specification and that undue experimentation would be involved in obtaining other dehydratase genes with which to practice the claimed invention.

Applicant's arguments filed 3/98 have been fully considered but they are not persuasive. It is stated that claim 2 is now drawn to a process using recombinant microorganisms transformed with a gene encoding glycerol dehydratase; the Examiner finds no such limitation in claim 2. It is stated in the response that although but a single example with the *Klebsiella dhaB* is presented the specification teaches methods for cosmid and gene isolation from other bacteria

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known to have dehydratase activity. It is noted that the claims are not directed to a method of isolating a *dhaB* gene from other species. A method of obtaining a gene does not enable production of a compound with a gene that may or may not be isolated by those methods. A gene is not described by its method of purification.

The rejection of claims 26-30 under 35 U.S.C. 112, first paragraph, is withdrawn, as Applicants have complied with the deposit requirement..

The rejections of claims 2 and 6 under 35 U.S.C. 112, second paragraph, is withdrawn, based upon the amendment.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 2 and 6 under 35 U.S.C. 102(b) as being anticipated by Tong *et al.* (1992; Appl. Biochem. Biotech.), is withdrawn, based upon the amendment.

The rejection of claim 31 under 35 U.S.C. 102(b) as being anticipated by Weinstock *et al.* is withdrawn, based upon the amendment.

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**Conclusion**

Claims 20-30 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 7:30 AM to 4:00 PM on weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Robert A. Wax, can be reached at (703) 308-4216.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 1800 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

geb

June 22, 1998

  
ROBERT A. WAX  
SUPERVISORY PATENT EXAMINER  
GROUP 180 1650